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February 13, 2003

TELECOPIER COVER SHEET

**FAX RECEIVED**  
**FEB 13 2003**  
**GROUP 1600**

TO: Examiner Cheyne Ly  
U.S. Patent and Trademark Office

TELECOPIER NO.: (703) 308-4242

FROM: Susan Hess  
Legal Assistant to Ferris Lander

PAGES INCLUDED: 7 (including cover sheet)

TELECOPIER NO.: (561) 625-6572

REGARDING: U.S. Patent Appln Serial No. 09/846,328  
Our Ref: 2132.051

**OFFICIAL**

SPECIAL INSTRUCTIONS:

Attached please find a Transmittal Letter and Response to Examiner's Office Action for the above-identified application.

Please contact me if you have any questions regarding this matter. Thank you for your assistance.

**PRIVACY AND CONFIDENTIALITY NOTICE**

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## CERTIFICATION OF FACSIMILE TRANSMISSION

I hereby certify that this paper is being facsimile transmitted to the Patent and Trademark Office on the date shown below to Examiner Cheyne Ly at (703) 308-4242.

Date: 2-13-03

Susan Hess  
Susan Hess

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICANT : JACKOWSKI et al.  
INVENTION: : BIOPOLYMER MARKER INDICATIVE OF DISEASE  
STATE HAVING A MOLECULAR WEIGHT OF  
2753 DALTONS  
SERIAL NUMBER : 09/846,328  
FILING DATE : April 30, 2001  
EXAMINER: : Ly, Cheyne  
GROUP ART UNIT : 1631  
ATTORNEY DOCKET NO. : 2132.051

TRANSMITTAL LETTER

Box Non-Fee Amendment  
Commissioner for Patents  
Washington, D.C. 20231

Sir:

Please find enclosed for filing:

- ☒ Response to Office Action of January 13, 2003  
☒ Please charge any deficiencies or credit any overpayment to Deposit Account No. 50-1803.

Date: 2/13/03

Respectfully submitted,

Ferris H. Lander 34616

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Date: 2-13-03Susan Hess  
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EXAMINER: : Ly, Cheyng

GROUP ART UNIT : 1631

ATTORNEY DOCKET NO. : 2132.051

#16  
Plunkett  
2/23/03RESPONSE TO OFFICE ACTION OF JANUARY 13, 2003

Box Non-Fee Amendment  
Commissioner for Patents  
Washington, D.C.

Sir:

In response to the Requirement for Restriction dated January 13, 2003, having a shortened statutory period for response set to expire February 13, 2003, kindly enter the following response:

Restriction to one of the following inventions has been required under 35 USC 121:

- I. Claims 1 and 2, are drawn to a biopolymer marker having a sequence identified as SEQ ID NO: 1 useful in indicating at least one particular disease state, classified in class 530, subclass 300.
- II. Claims 3-9, drawn to a method for evidencing and categorizing at least one disease state, classified in class 702, subclass 19.
- III. Claims 10-28 and 33-34, drawn to a diagnostic assay kit and method for determining the presence of the biopolymer marker or analyte thereof and determining risk-assessment, and identifying therapeutic avenues related to a disease state, classified in classes 422 and 436, subclasses 61 and 63. If this Group is elected, then the below summarized specific election is also required.
- IV. Claims 29-32, drawn to an antibody specific for the biopolymer marker having a sequence identified as SEQ ID NO: 1, classified in class 530, subclass 387.1.
- V. Claim 35, drawn to a process for regulating a disease state by controlling the presence or absence of a biopolymer including the sequence identified as SEQ ID NO: 1 or at least one analyte thereof, classified in class 514, subclass 2.

Applicants hereby elect, with traverse, the Group I invention, for further prosecution on the merits.

It is understood that claims 3-35, drawn to the non-elected invention, will remain pending, albeit withdrawn from further consideration in this application.

#### SUMMARY

This case is related, in claim format to several pending applications of which S.N. 09/846,352 is exemplary. After discussions with the Examiner in the '352 case, and subsequent

to a Restriction Requirement and subsequent rejoinder under *Ochai*, Applicants have received a Notice of Allowability that the following claims would receive favorable consideration:

**CLAIMS OF S.N. 09/846,352**

*Claim 1. A biopolymer marker peptide consisting of SEQ ID NO:1 diagnostic for Type II diabetes.*

*Claim 3. A method for diagnosing Type II diabetes comprising:*

*(a) obtaining a sample from a patient;*

*(b) conducting mass spectrophotometric analysis on said sample in a manner effective to maximize elucidation of discernible peptide fragments contained therein; and*

*(c) comparing mass spectrum profiles of a peptide consisting of SEQ ID NO:1 to mass spectrum profiles of peptides elucidated from said sample; wherein recognition of a mass spectrum profile in the sample displaying the characteristic profile of the mass spectrum profile for the peptide of SEQ ID NO:1 is diagnostic for Type II diabetes.*

*Claim 6. The method of claim 3, wherein the sample is an unfractionated body fluid or a tissue sample.*

*Claim 7. The method of claim 3, wherein said sample is selected from the group consisting of blood, blood products, urine, saliva, cerebrospinal fluid, and lymph.*

*Claim 8. The method of claim 3, wherein said mass spectrophotometric analysis is Surface Enhanced Laser Desorption Ionization (SELDI) mass spectrometry (MS).*

*Claim 9. The method of claim 3, wherein said patient is a human.*

*Claim 10. A Type II diabetes diagnostic kit comprising: (a) a peptide consisting of SEQ*

*ID NO:1 and (b) an antibody that binds to said peptide in a sample from a patient.*

*Claim 11. The diagnostic assay kit of claim 10, wherein said antibody is immobilized on a solid support.*

*Claim 12. The diagnostic kit of claim 10, wherein said antibody is labeled.*

Applicants thus traverse the requirement since claims of alternative scope have been deemed allowable in a single application.

In an effort to maintain equivalent scope in these applications, Applicants would respectfully request that the Examiner reconsider the requirement to include a similar grouping of claims. Applicants would elect such a group, without traverse, and file a supplemental amendment canceling all other pending claims and submitting a set of claims directed to the instantly disclosed invention, in a commensurate format to the claims allowed in the '352 application.

If the Examiner is amenable to these changes, please contact the undersigned via telephone, and a supplemental response will be filed immediately, via facsimile, in order to expedite prosecution.

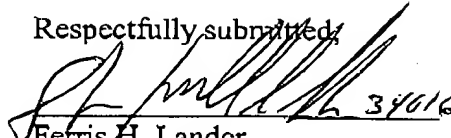
#### REMARKS/ARGUMENTS

Applicants have elected, with traverse, the Group I invention. It is respectfully requested that the Examiner permit Applicants to submit an amendment preliminary to further examination on the merits, in order to place on the record claims which have considered to represent a

permissible grouping for allowance within a single application in view of rejoinder under Ochai.

The Examiner's cooperation in this matter is greatly appreciated.

Respectfully submitted,

  
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